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The Canadian Cervical Cancer Screening Trial of human papillomavirus (HPV) testing versus Pap cytology

Submission date 09/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 05/01/2010	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.mcgill.ca/cccast/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-54063

Study information

Scientific Title
Efficacy trial of human papillomavirus (HPV) versus Pap testing for screening cervical cancer precursors: a randomised controlled trial

Acronym
CCCaST

Study objectives
Objectives:
1. To compare human papillomavirus (HPV) testing with Pap cytology to detect prevalent and early incident asymptomatic cervical cancers and their high-grade precancerous lesions among women aged 30 - 69 years who present for their routine cervical cancer screening in Montreal and Newfoundland
2. To identify individual, social, and health care delivery variables that influence the performance of the Pap smear and of HPV testing and determine the costs of delivery of those two screening strategies in the two populations chosen for the study

As of 05/01/2010 this record was updated; all details can be found under the relevant section with the above update date. At this point, the target number of participants field was also updated; the initial target number of participants at time of registration was 12,000. However, 14,953 women were assessed for eligibility and invited to participate and 10,154 were randomised into the trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Institutional Review Board of McGill University on the 26th April 2005. Ethics approval has been extended to several additional clinics and institutions involved in the study.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
More information can be found at http://www.mcgill.ca/cccast/

Health condition(s) or problem(s) studied
High-grade cervical intra-epithelial neoplasia

Interventions
Pap testing compared to HPV testing.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Biopsy-proven cervical intraepithelial neoplasia (CIN 2, 3) (high grade intraepithelial lesion [HSIL]) or cancer, ascertained at 6, 12, and 18 months

Secondary outcome measures
Biopsy-proven CIN 1 (low grade intraepithelial lesion [LSIL]) at 18 months.

Overall study start date
26/09/2002

Completion date
31/07/2007

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/01/2010:
1. Women aged 30 to 69 years
2. Sought screening tests for cervical cancer in any of 30 family practice or gynaecology clinics in Montreal and St. John's, Canada

Initial inclusion criteria at time of registration:
1. Women aged between 30 and 69 years
2. Currently attending a colposcopy clinic for evaluation, treatment or follow up of a cervical lesion

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
10,154 randomised into trial

Key exclusion criteria
Current exclusion criteria as of 05/01/2010:
1. Currently being followed up for a cervical lesion
2. Lacked a cervix
3. Pregnant
4. Had a history of cervical cancer
5. Had undergone Pap testing in the previous year
6. Unable to provide consent were excluded (note that this is related also to the ability to understand French or English)

Initial exclusion criteria at time of registration:
1. Without a cervix
2. Pregnant
3. History of cervical cancer
4. Known human immunodeficiency virus (HIV) infection
5. Mentally incompetent
6. Unable to understand French or English
7. Refuse to provide an informed consent

Date of first enrolment
26/09/2002

Date of final enrolment
31/07/2007

Locations

Countries of recruitment
Canada

Study participating centre
Division of Cancer Epidemiology
Montreal
Canada
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Sponsor information

Organisation

McGill University (Canada) - Research Grants Office

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845 Sherbrooke Street West
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Sponsor type
University/education

Website
http://www.mcgill.ca/

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-54063)

Funder Name
Merck-Frosst (Canada) - unrestricted educational grant

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/08/2006		Yes	No
Results article	results	18/10/2007		Yes	No